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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,041	11/04/2003	Benjamin Oshlack	200.1133CON2	6154

7590 07/28/2008  
DAVIDSON, DAVIDSON & KAPPEL, LLC  
14th Floor  
485 Seventh Avenue  
New York, NY 10018

EXAMINER
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ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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07/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Interview Summary

Application No.

10/701,041

Applicant(s)

OSHLACK ET AL.

Examiner

JAMES H. ALSTRUM  
ACEVEDO

Art Unit

1616

All participants (applicant, applicant's representative, PTO personnel):

(1) JAMES H. ALSTRUM ACEVEDO.

(3) Mr. Oleg Ioselevich, Esq..

(2) Ms. Humera Sheikh (Primary).

(4) Mr. Phillip C. Strassburger, Esq..

Date of Interview: 22 July 2008.

Type: a) ☒ Telephonic b) ☐ Video Conference

c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.

If Yes, brief description: Mr. Ioselevich discussed how the morphology of a lollipop having a candy shell and a gum "core" was morphologically analogous to Applicants' invention described, for example, in claim 62 of application 10/701,041, wherein the composition comprises an inert core coated with a first layer and second layer.

Claim(s) discussed: Claims 62 and 65 of 10/700,041; Claims 62 and 63 of 10/700,861.

Identification of prior art discussed: Palermo (WO 99/32120); Elger et al. (USPN 4,844,907); and Granger et al. (USPN 5,149,538).

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1618  
Examiner's signature, if required

Examiner Note: You must sign this form unless it is an  
Attachment to a signed Office action.

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

#### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

#### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Mr. Ioselevich described the teachings of Palermo's (i.e. cited prior art reference) invented compositions, which were designed to release both opioid antagonist and opioid agonist upon oral ingestion or dissolution with solvent, which is different than Applicants' invented compositions that were designed to sequester opioid antagonist, when Applicants' invented composition is taken orally. Mr. Ioselevich also emphasized that Applicants' invented compositions were characterized by the release of opioid antagonist upon tampering (e.g. crushing or other physical perturbation) and that the finite amount of opioid antagonist that could leach from Applicants' invented compositions is insufficient to yield a measurable physiological effect. Mr. Ioselevich also pointed out that the amount of opioid antagonist that could leach would not yield the same physiological effects as a controlled-release or sustained release composition comprising the same opioid antagonist. Regarding the Elger reference (USPN 4,844,507), Applicants' attorney, Mr. Ioselevich, indicated that bilayer dosage forms are generally formed by pressing two different layers together and thus yield a dosage form that is morphologically distinct from the morphology of Applicants' claimed compositions. Concerning the Granger reference (USPN 5,149,538), Mr. Ioselevich argued that Granger clearly teaches that opioid antagonist is released upon oral ingestion or contact of Granger's formulations with water or alcohol, which is different from Applicants' invented compositions that do not release appreciable quantities of opioid antagonist unless Applicants' dosage form is physically tampered with (e.g. crushed). The Examiner's suggested Applicants clarify that all their claims are drawn to oral dosage forms. Additional possible claim amendments were discussed and the Examiners indicated that these would be considered upon receipt of Applicants' submission of written responses to the outstanding office actions.